K122016

MAR 0 1 2013

Attachment 3

Section 5: 510(k) Summary

1. 510(k) Owner:

Metabiomed, Inc.
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USA
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2. Company Contact: Ian Yun
   Title: Sales Director

3. 510(k) Preparer:

Blix Winston
ACMD Consulting, LLC.
2600 Mullinix Mill Road
Mt. Airy, MD 21771
USA
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4. Date of Submission: July 7, 2012

5. Device Name and Classification:

Trade name – REXTAR LCD
Common name - Portable X-Ray System
Classification name - Extraoral source x-ray system

6. Predicate Devices:

Manufacturer :	Genoray Co. Ltd.
Device :	PORTX-II
510(k) Number :	K063121 (Decision Date - 01/11/2007)

Manufacturer:	Digimed Corporation
Device:	DIOX
510(k) number:	K082167 (Decision Date- 04/08/2011)

7. Classifications Names & Citations:

21CFR 872.1800, EHD - Extraoral source x-ray system, Class 2

8. Compliance with performance standards.
   All components to which the standard applies are certified to conform to diagnostic equipment standards, 21 CFR 1020.30 and 1020.31.

9. Device Description:

   a. General:
      The REXTAR LCD consists of an X-ray tube, X-Ray tube assembly, X-Ray Controller built into a hand held camera-like device.

   b. Outline:

      The REXTAR LCD is an extraoral source x-ray system with a DC-powered device that produces x-rays and is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The x-ray source a, X-ray camera, is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

   c. Features:

      REXTAR LCD is a portable X-ray system that has the following qualities:

      - High Frequency X-ray Generator (70kV-2mA Fixed)
      - High Quality Toshiba Tube used (Tube Focal Spot (0.4mm))
      - Target Angle 12°
      - Easy to Move
      - Eliminates the need for multiple X-Ray units in doctor's office
      - Efficient to use
      - Compact Size & Light Weight Design for Ultimate Portability
      - Long Battery Life - Hundreds of images can be obtained from one time charge
      - Diverse Applications (Field Hospital, Emergency, Forensic Science, Operation Room)
      - Can use conventional film or digital sensors to obtain images
      - Images from digital sensors are displayed on a computer that is not included as a part of the camera for the Rextar LCD

- REXTAR also has:
  - Compatibility with all Digital Sensors All Digital Imaging Sensor (USB Type) existing in the world can be used for Rextar LCD unlike other products.
  - Easy & Simple Installation by USB Memory Stick & ODD, Memory Cards (SD,MMC)
  - Samsung Ultra Q1 (UMPC) Embedded
  - Wireless data transmission has Not been tested with this device and should not be used

d. Operating principle:

Operating principle is that X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor).

10. Indications for use:

REXTAR LCD is a portable X-ray system to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.

11. Substantial equivalence:

The REXTAR device had been tested to demonstrate substantial equivalence with the predicate devices. A comparison of features is included below.

Comparison Table: REXTAR LCD and the Predicate Devices

Parameter	Rextar LCD	PORTX-II	DIOX
510(k)	Submitted for marketing clearance	K063121	K103600
Intended Use	REXTAR LCD is a portable X-ray system to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.	To be used by trained dentists and dental technicians a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.	To be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.
Indications	X-ray system designed to provide images of the patients undergoing dental procedures. Clinical uses include Bite wing, periapical, occlusal and panoramic images.	X-ray system designed to provide images of the patients undergoing dental procedures. Clinical uses include Bite wing, periapical, occlusal and panoramic images.	X-ray system designed to provide images of the patients undergoing dental procedures. Clinical uses include Bite wing, periapical, occlusal and panoramic images.
Dentist/dental assistant Involvement	Supervision	Supervision	Supervision
Labeling	Submitted	Original, Cleared	Original, Cleared

X-ray Generator	High-Frequency	High-Frequency	High-Frequency
Tube Power	70kV /2mA	60kV /2mA	60kV /2mA
Tube Type	Stationary	Stationary	Stationary
Tube Focal Spot	0.4mm	0.8 mm	0.8 mm
Target Angle	12°	20 °	20°
Exposure Time	0.01 ~ 1.3 (sec) (43 Steps)	0.02 ~ 2.00 (sec) (24Steps)	0.01~ 1.60 (sec) (0.01 sec/ step)
Parameter	Rextar LCD	PORTX-II	DIOX
Power Requirement	DC 11.1 V	DC 22.2V	DC 24 V
Weight (kg)	1.88	2.95	1.80
Picture Quality	Good	Normal	Normal
Battery Type	Rechargeable	Rechargeable	Rechargeable
Digital Sensor	X	X	X
LCD	LCD Panel Display (4 Digits, 0.5 Inch Character Height)	X	X
Chipset & Graphics		X	X
Memory		X	X
Storage		X	X
Communica -tions		X	X

11. Standards:
The portable x-ray system, REXTAR LCD, will comply with applicable requirements of the Underwriters Laboratories Standard for Safety-UL/IEC 60601-1, IEC 60601-2-7, IEC 60601-2-28 and IEC 60601-2-32.
EMC testing was conducted by (EMC Compliance Co., Ltd. in accordance with Standard EN/IEC 60601-1-2). All test results were satisfactory.

A complete list of performance standards is listed below.

No.	OEN	Reference	Title of standard	Year of ratificatio
1	IEC	IEC 60601-1	Medical electrical equipment-Part 1:	1990
2	IEC	Amendment A1 to EN 60601-1	Medical electrical equipment-Part 1: General requirement for safety	1991
3	IEC	Amendment A2 to EN 60601-1	Medical electrical equipment-Part 1:	1995
No.	OEN	Reference	Title of standard	Year of ratificatio
4	IEC	IEC 60601-1-2	Medical electrical equipment-Part 1: General requirement for safety – 2 Collateral standard: Electromagnetic Compatibility - Requirements and test.	2001
5	IEC	IEC 60601-1-3	Medical electrical equipment-Part 1: General requirement for safety – 3 Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment.	1994
6	IEC	IEC 60601-1-4	Medical electrical equipment-Part 1: General requirement for safety – 4 Collateral standard: Programmable electrical medical systems	1996
7	IEC	IEC 60601-2-7	Medical electrical equipment-Part 2: Particular requirements for the safety of High-voltage generators of diagnostic X-ray generators	1998

8	IEC	IEC 60601-2-28	Medical electrical equipment-Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	1993
9	IEC	IEC 60601-2-32	Medical electrical equipment-Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	1995
10	Cenelec	EN 980	Graphical symbols for use in the labeling of medical	2003
11	Cenelec	EN 1041	Information supplied by the manufacturer with medical devices	1998
No.	OEN	Reference	Title of standard	Year of ratificatio
12	ISO	ISO 14971	Medical devices – Application of risk	2007
13	ISO	ISO 13485	Medical devices. Quality management systems. Requirements for regulatory purposes	2003
14	FDA	21 CFR 1020.30 and 1020.31	Diagnostic equipment standards	N/A

12. Conclusion: Based on comparison with the predicate devices and the results of testing Metabiomed believes its REXTAR LCD device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Meta Biomed, Incorporated
C/O Mr. Blix Winston
ACMD Consulting, Limited Liability Company
2600 Mullinix Mill Road
MOUNT AIRY MD 21771

Re: K122016
Trade/Device Name: REXTAR LCD
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: II
Product Code: EHD
Dated: February 7, 2013
Received: February 12, 2013

Dear Mr. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known): K122016

Device Name: REXTAR LCD

Indications for Use:

REXTAR LCD is a portable X-ray systems to be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ___X___ AND.OR Over-The-Counter Use: _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Mark S. Hurwitz -S

2013.02.22 11:44:41 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122016